

## **REMARKS**

### **The Amendments**

The specification is amended to address the objections thereto in the Office Action. No new matter is added.

Claim 1 is canceled and the claims are directed to the embodiments under independent claim 5. Claim 5 is amended for clarification that the optional forms of pramipexole (previously recited in claim 8) are optional in the independent claim. The scope of claim 5 is not narrowed. The claims are otherwise amended to conform with these amendments, to correct non-substantive informalities and to add additional dependent claims fully supported by the disclosure.

Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

### **The Objections to the Disclosure**

The objections to the disclosure, i.e., the Brief Description of Drawings and Abstract, are believed to be overcome by the above amendments.

### **The Provisional Obviousness-type Double Patenting Rejection**

The provisional rejection of claims 1-11 for obviousness-type double patenting over claims 1-11 of copending application, Ser. No. 10/935,508, is respectfully traversed. The instant application has an effective US filing date before the copending '508 application. In accordance with MPEP §804(I)(B)(1), the provisional obviousness-type double patenting rejection in this earlier filed application should be withdrawn thereby permitting this application to issue without need of a terminal disclaimer. A terminal disclaimer is only required in the later-filed application. This application, being the earliest, does not require a terminal disclaimer. Accordingly, the provisional rejection should be withdrawn.

**The Rejection under 35 U.S.C. §112, first paragraph**

The rejection of claims 1-11 under 35 U.S.C. §112, first paragraph, is respectfully traversed.

Applicants do not understand the allegation in the Office Action that the claims are not clear and that they merely provide a "laundry list" disclosure. The claims are quite specific in nature both as to the disease/condition treated and the active compound used for the treatment. The claims recite a method for "treating obesity in a subject ranging from 6 to 18 years old and having type 2 diabetes," which is quite specific as to the particular disease/condition and particular class of patient. Further, the method comprises "administering to the subject a pharmaceutical composition comprising an effective amount of pramipexole" or common forms thereof, e.g., salts, which is very specific as to the compound. The allegations in the Office Action that the claims are directed to broad genus' without sufficient disclosure of representative species to support such genus' are, thus, not believed to reflect the actual nature of the claims herein. Neither the disease/condition treated in the claims nor the active compound for such treatment recite a broad genus. To the contrary, they are both very specific.

The rejection was made over claims essentially as originally presented in the application (the amendment to claim 5 does not change the scope of the claim). In accordance with MPEP §2163(I)(A), there is a strong presumption in this situation that an adequate written description of the claimed invention is present when the application is filed and the PTO has the burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims; see, e.g., In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976). Applicants understand that the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. But the instant facts do not fall under any of the situations described in MPEP §2163 – e.g., genes, a compound described merely by its function or element described by a "laundry list" – for when original claims lack adequate written description.

Further, no evidence or apparent reasons have been presented by the PTO to meet the

burden of showing why one of ordinary skill in the art would not recognize from applicants' disclosure the invention being claimed. The Office Action states (bottom of page 5) that one of ordinary skill in the art "would reasonably require a more detailed description because those subject encompassed in both claims 1 and 5 would reasonable [sic] be expected to have altered metabolic processes or rates, as compared to nondiabetics or to an adult population." Applicants fail to see how this fact, if assumed true, evidences that one skilled in the art would not recognize that the applicant had possession of the invention being claimed. Claim 5 clearly describes a specific patient class which would be readily identifiable to one of ordinary skill in the art, without the need of any further detailed description. Claim 5 also describes the specific drug used for the treatment and one of ordinary skill in the art would need no further detailed description on this point to recognize possession of the invention.

Regarding the allegation that the disclosure fails to provide working examples, applicants respectfully point out that working examples are not necessary to support claims under 35 U.S.C. §112, first paragraph. See, e.g., In re Borkowski, 422 F.2d 904, 164 USPQ 642 (CCPA 1970); and, In re Angstadt, 537 F.2d 498, 190 USPQ 214 (CCPA 1976). Furthermore, the disclosure does provide working examples of an animal model for treatment of obesity which is sufficiently representative of the invention to inform one of ordinary skill in the art of applicants' possession of the invention claimed. The examples described on pages 5-6 and Figures 1-2 of the disclosure show applicants' possession of the invention through an animal model reasonably correlated to the claimed method of treating obesity. Thus, even though examples are not required, the animal model examples here further bolster the adequacy of the written description of the claimed invention.

For all of the above reasons, applicants urge that the disclosure provides a fully adequate description from which one of ordinary skill in the art would recognize the invention and recognize that such was described by applicants. Thus, the rejection under 35 U.S.C. §112, first paragraph, for lack of written description should be withdrawn.

**The Rejection under 35 U.S.C. §103**

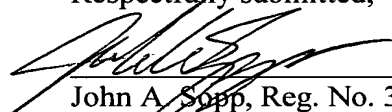
The rejection of claims 1-4 and 6-9 under 35 U.S.C. §103 for obviousness over Berger (WO 01/41763) is respectfully traversed.

It is believed that the rejection is rendered moot by the above amendment since claim 5 was not included in the rejection and the claims have been amended such that claim 5 is the sole remaining independent claim from which all other claims ultimately depend. It appears to have been recognized in the Office Action that Berger fails to teach or suggest a method for treating obesity in a subject ranging from 6 to 18 years old and having type 2 diabetes. Accordingly, applicants respectfully submit that Berger fails to render the instant claims obvious to one of ordinary skill in the art. Thus, the 35 U.S.C. § 103 rejection thereover should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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Authority 37 C.F.R. §1.34

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